

Submitting a Clinical Trial Safety Report

Significant Safety Issue Notification

To be completed and sent to the HREC for all clinical trials (therapeutic goods and non-therapeutic goods), SSIs that have been implemented as an urgent safety measure should be reported within **72 hours** of the sponsor becoming aware of the issue.

All other SSIs should be reported within **15 Calendar days** of the sponsor becoming aware of the issue

An SSI is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial:

- ❖ Urgent Safety Measure: A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.
- ❖ Temporary Halt of a Trial for Safety Reasons.
- ❖ Early Termination of the Trial for Safety Reasons.
- ❖ Amendment (submit through the Notification of an Amendment to a Research Study form).

Reporting Local Safety Events to the Institution

To be completed for all clinical trials (therapeutic goods and non therapeutic goods).

This form should be completed by the Principal Investigator with notification to their Research Governance Office

(RGO) when in the opinion of the investigator one of the following events has occurred at the site:

- ❖ A Suspected Unexpected Serious Adverse Event (SUSAR) in a medicines or biological trial.
- ❖ An Unanticipated Serious Adverse Device Event (USADE) in a medical device trial.
- ❖ An Unexpected and Related Serious Adverse Event (URSAE) in any other interventional trial.

This form should be sent to the RGO within **72 hours** of the site becoming aware of the event.

Sponsors directly submitting to the HREC.

Annual Safety Reporting, Investigator's Brochure Updates/Addenda:

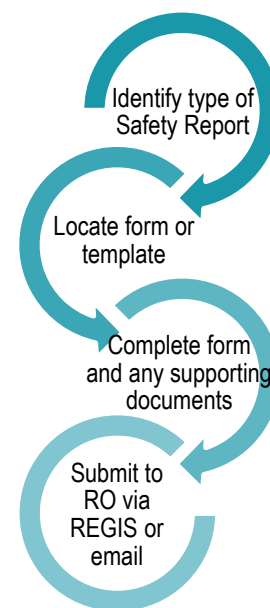
Sponsors may provide annual safety reports or updated IBs with a cover sheet. These should be emailed directly to the Research Office managing the application.

Sponsors must ensure that all reports/documents sent to the HREC (where standard templates are not available) adequately identify the trial and provide some context in relation to the HREC's role, such as the impact on patient safety, trial conduct and/or trial documentation*.

***Note:** Any changes to trial documents (e.g. protocols, PICFs, updated IBs) should be provided to the HREC using

the standard amendment reporting process.

How does it work in REGIS?



Significant Safety Issue Notification

The Project Owner (CPI for ETH) has full access to complete and is **the only person who can submit the Significant Safety Notification Issue form**. The Owner is able to give edit and view permissions to others.

Any person who had been granted Edit permissions during the application process (pre-approval) will continue to have access to the project (post approval). **Editors can complete the notification form but cannot submit.**

The notification form can be saved using the 'save' icon at any time and completed at a later date. Once saved, the Significant Safety Issue Notification will stay 'In Progress' for up to 365 days.



Form Status

- **In Progress** Form is with the applicant for completion or editing.
- **Submitted** Form is with the research office.
- **Approved** Form has been reviewed and approved. An email notification will be sent to the CPI.

Complete & submit to the HREC

Step 1. Locate project

Click the 'Projects' icon to see all projects.



Click the required Project 'Identifier' (PID) or 'Title' in the list of projects

Step 2. Select the Ethics Project

This is where you can manage post approval activity (e.g. amendment and safety). Only an approved study can have a safety notification created.

Click on the Ethics (ETH) identifier

Identifier

2018/ETH00061

Or click on the (option icon) next to the Identifier and then select. **Project information**.

Both of these options will take you to the Project Information page

Step 3. Open a new Form

Select 'Form' from the left-hand menu.



Select '+ New form'

+ New form

Select the form to be submitted.

Significant Safety Issue Notification

Step 4. Complete the form

The **Project Details** section of the form will pull through information already available in the system.



Add the **date the SSI occurred** by selecting the calendar icon or manually typing in the date in the DD/MM/YYYY format.

Select the **Report Type** from the options available.

Select the **Form Type** from the drop down menu. SSI types are described on page 1 of this document.

Depending on the answers provided the form will display additional questions or sections.

Answer each question and progress to the next section.

Step 5 Document Uploads

Document uploads



If there are no documents to upload select the checkbox and then the minus icon.

Document Type: select from the dropdown.

Document Descriptor: 20 characters max.

Document Version and Date: version and date of the document (normally listed in footer). If no version or date add version 1 and the date the report is being submitted.



To add additional documents, select the plus icon and a new line will appear.

DO NOT upload documents to be reviewed by the HREC as an Amendment. Please provide details of the amendment by completing the 'Notification of an Amendment Form', select the 'General Amendment' option and submit it contemporaneously with this notification.

Step 6

If you are the CPI you will be able to submit the SSI by clicking submit.

Submit

If you are not the CPI save the form by selecting the save icon.



Notify the CPI that the SSI can now be submitted.

Step 7

The SSI has been submitted to the HREC when the status of the form changes to "Submitted".

When the SSI has been acknowledged the status of the form changes to "Approved".

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).

Reporting Local Safety Events to the Institution

To be completed for all clinical trials (therapeutic goods and non-therapeutic goods)

Type of event: Suspected Unexpected Serious Adverse Events (SUSARs) and Unanticipated Serious Adverse Device Effects (USADEs) occurring at the site:

- ❖ *A Suspected Unexpected Serious Adverse Event (SUSAR) in a medicines or biologicals trial.*
- ❖ *An Unanticipated Serious Adverse Device Effect (USADE) in a medical devices trial.*
- ❖ *An Unexpected and Related Serious Adverse Event (URSAE) in any other interventional trial.*

Who submits: Principal Investigator.

To where/whom: The RGO for the site where the event occurred.

When: Within 72 hours of the PI becoming aware of the event.

How: The [SUSAR/USADE/URSAE Notification Form](#) must be used and emailed directly to the RGO.

Note: it is anticipated that this form will become available in REGIS in the future. This QRG will be updated once available.

Sponsors directly submitting to the HREC

Type of event: Annual Safety Reporting, Investigator's Brochure and Updates/Addenda

Who submits: Sponsors may provide annual safety reports or updated IBs/Addenda with a cover sheet.

The Coordinating Principal Investigator can also provide these safety reports.

To where/whom: These should be emailed directly to the Research Office managing the application.

When: IB's as and when updates are generated. Annual safety reporting aligned with the annual progress report sent to the HREC or with the safety reporting cycles of global companies.

How: Directly to the research office managing the application via email, ensure that all reports/documents sent to the HREC (where standard templates are not available) adequately identify the trial and provide some context in relation to the HREC's role; such as the impact on patient safety, trial conduct and/or trial documentation*.

***Note:** Any changes to trial documents (e.g. protocols, PICFs, updated IBs) should be provided to the HREC using the standard amendment reporting process.

Note: it is anticipated that this functionality will become available in REGIS in the future. This QRG will be updated once available.

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).